DOI: 10.1111/jdv.19521

POSITION STATEMENT



Position statement of the EADV Artificial Intelligence (AI) Task Force on AI-assisted smartphone apps and web-based services for skin disease

Tobias E. Sangers ¹ 💿 Harald Kittler ² 💿 Andreas Blum ³ Ralph P. Braun ⁴ 💿
Catarina Barata ⁵ Alessandra Cartocci ⁶ 💿 Marc Combalia ⁷ 💿 Ben Esdaile ⁸
Pascale Guitera ^{9,10,11} 🖻 Holger A. Haenssle ¹² 🗈 Niels Kvorning ¹³ 🗈 Aimilios Lallas ¹⁴ 🗈
Cristian Navarrete-Dechent ¹⁵ 💿 Alexander A. Navarini ¹⁶ 💿 Sebastian Podlipnik ^{17,18} 💿
Veronica Rotemberg ¹⁹ H. Peter Soyer ²⁰ Linda Tognetti ²¹ Philipp Tschandl ²
Josep Malvehy ^{22,23} on behalf of the EADV AI Task Force

¹Department of Dermatology, Leiden University Medical Center, Leiden, The Netherlands

²Department of Dermatology, Medical University of Vienna, Vienna, Austria

³Public, Private and Teaching Practice of Dermatology Konstanz, Konstanz, Germany

⁴Department of Dermatology, University Hospital Zurich, Zurich, Switzerland

⁵Institute for Systems and Robotics, LARSyS, Instituto Superior Técnico, Universidade de Lisboa, Lisboa, Portugal

⁶Department of Medical Biotechnologies, University of Siena, Siena, Italy

⁷Kenko.ai, Barcelona, Spain

⁸Department of Dermatology, Whittington NHS Trust, London, UK

⁹Faculty of Medicine and Health, The University of Sydney, Sydney, New South Wales, Australia

¹⁰Sydney Melanoma Diagnostic Centre, Royal Prince Alfred Hospital, Camperdown, New South Wales, Australia

¹¹Melanoma Institute Australia, The University of Sydney, Sydney, New South Wales, Australia

¹²Department of Dermatology, Heidelberg University Medical Center, Heidelberg, Germany

¹³Department of Plastic Surgery, Herlev Hospital, Herlev, Denmark

¹⁴First Department of Dermatology, Faculty of Health Sciences, School of Medicine, Aristotle University, Thessaloniki, Greece

¹⁵Melanoma and Skin Cancer Unit, Department of Dermatology, Escuela de Medicina, Pontifica Universidad Catolica de Chile, Santiago, Chile

¹⁶Department of Dermatology and Department of Biomedical Engineering, University Hospital of Basel, Basel, Switzerland

¹⁷Department of Dermatology, Hospital Clínic, University of Barcelona, Barcelona, Spain

¹⁸Institut d'Investigacions Biomèdiques August Pi i Sunyer (IDIBAPS), Barcelona, Spain

¹⁹Division of Dermatology, Department of Medicine, Memorial Sloan Kettering Cancer Center, New York, New York, USA

²⁰Frazer Institute, Dermatology Research Centre, The University of Queensland, Brisbane, Queensland, Australia

²¹Dermatology Unit, Department of Medical, Surgical and Neurosciences, University of Siena, Siena, Italy

²²Melanoma Unit, Dermatology Department, Hospital Clínic de Barcelona, IDIBAPS, Universitat de Barcelona, Barcelona, Spain

²³Centro de Investigación Biomédica en Red de Enfermedades Raras (CIBERER), Barcelona, Spain

Correspondence

Tobias E. Sangers, Department of Dermatology, Leiden University Medical Center, Albinusdreef 2, 2333 ZA Leiden, The Netherlands. Email: t.e.sangers@lumc.nl

Abstract

Background: As the use of smartphones continues to surge globally, mobile applications (apps) have become a powerful tool for healthcare engagement. Prominent among these are dermatology apps powered by Artificial Intelligence (AI), which

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes. © 2023 The Authors. *Journal of the European Academy of Dermatology and Venereology* published by John Wiley & Sons Ltd on behalf of European Academy of Dermatology and Venereology. provide immediate diagnostic guidance and educational resources for skin diseases, including skin cancer.

Objective: This article, authored by the EADV AI Task Force, seeks to offer insights and recommendations for the present and future deployment of AI-assisted smartphone applications (apps) and web-based services for skin diseases with emphasis on skin cancer detection.

Methods: An initial position statement was drafted on a comprehensive literature review, which was subsequently refined through two rounds of digital discussions and meticulous feedback by the EADV AI Task Force, ensuring its accuracy, clarity and relevance.

Results: Eight key considerations were identified, including risks associated with inaccuracy and improper user education, a decline in professional skills, the influence of non-medical commercial interests, data security, direct and indirect costs, regulatory approval and the necessity of multidisciplinary implementation. Following these considerations, three main recommendations were formulated: (1) to ensure user trust, app developers should prioritize transparency in data quality, accuracy, intended use, privacy and costs; (2) Apps and web-based services should ensure a uniform user experience for diverse groups of patients; (3) European authorities should adopt a rigorous and consistent regulatory framework for dermatology apps to ensure their safety and accuracy for users.

Conclusions: The utilisation of AI-assisted smartphone apps and web-based services in diagnosing and treating skin diseases has the potential to greatly benefit patients in their dermatology journeys. By prioritising innovation, fostering collaboration and implementing effective regulations, we can ensure the successful integration of these apps into clinical practice.

INTRODUCTION

With a staggering 6.4 billion smartphone users worldwide, mobile applications possess the capability to engage nearly 80% of the global population. Shortly after the launch of the Apple App Store and Google Play Store in 2008, the first dermatology-centric apps emerged, offering valuable information to the public. Initially, these apps focused on providing educational content, such as the visual manifestations of skin cancer, akin to the hard-copy materials distributed to patients.¹ In recent years, however, advancements in the field of AI are increasingly enabling smartphone users to monitor and receive direct diagnostic advice on skin conditions via smartphone apps and web-based services (e.g. assessing skin lesions for signs of skin cancer using the smartphone camera).² The pool of end-users (or target audience) of the currently available apps can vary widely: consumers (e.g. the general population or patients with limited medical knowledge), non-dermatology primary care providers and dermatology healthcare professionals. As the implementation progresses, there has been a growing divergence of concerns regarding potential harms and simultaneous optimism for improved patient care.^{3,4} Along with AI-assisted diagnostic apps, companies have also initiated AI as a tool to improve education in dermatology.

This article, authored by the EADV Artificial Intelligence Task Force, seeks to offer insights and recommendations for the present and future deployment of AI-assisted smartphone applications (apps) and web-based services for skin diseases with emphasis on skin cancer detection. The recommendations presented herein aim to provide guidance for clinicians, researchers, consumers, app developers, (inter)national professional dermatology societies and regulators ensuring the safe and proper implementation of this technology worldwide.

METHODOLOGY

The initial concept for the position statement was drafted by T.S. and J.M., who performed a comprehensive literature review to inform the initial draft. To ensure a well-informed and balanced perspective, two rounds of digital discussions were hosted, during which members of the EADV AI Task Force provided input and feedback. The feedback received from these discussions was meticulously reviewed and analysed, and appropriate revisions were made to the initial draft to ensure its accuracy, clarity and relevance.

CONSIDERATIONS OF THE TASK FORCE

Risks through inaccuracy

The integration of AI into publicly available apps has led to concerns about possible risks due to inaccuracy. Smartphone apps may cause significant adverse events through inaccurate predictions, which can be falsely reassuring or falsely concerning. In fact, recent studies have shown generally poor accuracy of these apps in terms of sensitivity and/or specificity in detecting skin cancer.^{4–6}

Quality, quantity and variance of image training data

One of the factors that may contribute to this poor accuracy is the quality, variance and quantity of image training data used to develop and validate AI algorithms. To ensure adequate training, image data should include skin conditions relevant to the target population, along with patient-level contextual information.^{7,8} Especially for apps and web-based services that are primarily intended to be used by consumers, it is expected that a large variety of lesion types will be photographed for signs of skin cancer (e.g. inflammatory lesions, scars, angioma, benign nevi). A significant issue is the handling of outof-distribution (OOD) cases, where an algorithm encounters inputs that are not, or not well, represented in the training data.9 These cases can lead to unpredictable and potentially harmful outcomes, as the AI system may not have been adequately exposed to similar examples during its training phase. Therefore, the training data for apps should not only include the target condition (e.g. skin cancer) but also remaining types of lesions that the user may photograph, and potentially even unaffected normal skin. Optimally, the applications should include unusual presentations of common neoplasms including rare subtypes, as well as rare malignant neoplasms that may initially mimic benign skin lesions (e.g. early Merkel cell carcinomas) to avoid potential biases that could result in inaccurate outcomes.^{10,11} The training data should include images captured using a variety of hardware (cameras) and software (image capturing applications) from the intended setting where the final algorithms will be used.^{7,12} To avoid adverse events from algorithm bias in applications intended towards consumers, the training library should include a large number of non-professional photographs taken by consumers. This information can help to ensure that an AI algorithm can be adequately trained based on the relevant skin conditions in the target population and a variety of image sources. By including layperson-level contextual information, algorithms can also take into account other factors that may affect the appearance of skin conditions, such as age, skin tone, medical history (e.g. history of skin cancer) and the appearance of skin disease relative to other lesions on the body (e.g. compare an atypical nevus to other nevi on the skin). In this way, the training data should be representative of the target population, skin conditions and image capturing techniques and reflective of the real-world context in which the app will be used, thus ensuring a reliable and accurate diagnosis. Ensuring an AI system is reliable requires extensive validation and ongoing monitoring

to ensure consistent performance across a wide range of real-world conditions.

Ensuring reliable performance in diverse image capture conditions, devices and populations

Reliability is also a concern, as AI algorithms can sometimes produce inconsistent results when confronted with subtle differences in input data. Factors such as lighting conditions, image resolution, camera angles and other issues like out-of-focus photos, photos taken too close or too far away from a given skin lesion have the potential to result in incorrect diagnoses or false positives. Related to this concern, research has demonstrated a difference in accuracy depending on which smartphone brand is used for an assessment (e.g. Apple iOS, Android).^{12,13} This is possibly due to differences in camera hardware (e.g. lenses, sensors, colour temperature can vary between smartphone camera models) between devices, as well as automated pre- and postprocessing on devices. This means that app developers should additionally validate for different smartphone hardware and software versions to ensure consistent results across all device types, models and brands. Furthermore, it is important for apps to have the capability to evaluate the quality of the images and to provide feedback to the consumer and/or refrain from analysis if the image quality is insufficient to perform a reliable assessment.

Another factor that may affect accuracy is variability in performance across different skin tones. Research suggests suboptimal accuracy of diagnostic AI models for darker skin tones compared to lighter ones,^{14,15} possibly due to underrepresentation of skin lesion images of patients with a darker skin tone in the training data.¹⁶ To avoid health disparities based on skin tone, smartphone apps should deliver consistent accuracy for all skin tones or clearly state if they are unable to do so. Optimally, users of the application should be both informed of its inability to evaluate various skin tones both in the terms-of-use and during attempts to evaluate out of distribution skin tones.

Risk-benefit assessment

While it is challenging to state the minimally acceptable accuracy that these apps should offer, the task force emphasizes the importance of evaluating these apps based on their overall benefits while minimising potential risk and potential burden on the overall healthcare system derived from these apps.^{6,17–19} Currently, there is a distinct lack of studies that demonstrate this benefit–risk relationship. We recommend that studies should be performed prospectively, in the intended-use setting, with outcome measures directly related to the benefits of patients. As of now, due to this lack of convincing evidence, the task force refrains from recommending diagnostic smartphone apps with diagnostic capabilities to consumers until evidence from

impartial prospective clinical trials within the intendeduse setting is available. Moreover, caution is imperative when implementing these apps at the population level, for example by healthcare insurers, as they may have adverse consequences for the patients' health and safety, while simultaneously increasing the workload among both primary and secondary care providers.

Explainable AI

Explainability may be crucial for gaining trust in AI systems, as users, especially healthcare professionals, need to understand the rationale behind an AI-generated diagnosis because so far the medico legal responsibilities are still with the health professional. The European Ethics guidelines for trustworthy AI specifically recommend the explanation of AI systems and their decisions, tailored to the stakeholder's needs.²⁰ However, AI algorithms, particularly deep learning models, are often seen as 'black boxes' because their decisionmaking processes can be opaque and difficult to interpret.²¹ The development of explainable AI techniques specifically designed with the end-user in mind is necessary to provide transparent explanations of algorithmic decisions, enabling users to gain insights into the influencing factors of diagnosis, and further research is needed to assess their impact on diagnostic decision-making.22

Incorporating human preferences

A recent study revealed that physicians' personal judgements about the potential outcomes of management decisions can enhance AI-based diagnostic support for skin cancer.²³ Although these preferences are usually not considered in the development of AI tools, they should be accorded greater importance in the future.

Risks of improper user education

While most apps issue disclaimers that their results should not substitute medical professional advice, a lack of education and adequate information for users on the proper selection of lesions suspicious for skin cancer can lead to false reassurance or unnecessary concern. Furthermore, the task force considers it likely that consumers will use AI-powered apps beyond their stated purpose and view the app result as a substitute for a consultation with a healthcare professional, leading to a potentially large impact of these apps on health outcomes. Given the significant potential impact these apps can have on the patient journey, there is a large impact of incorrect lesion selection by different types of users, and efforts to mitigate this need to be evaluated. Furthermore, discrepancies between app developers' stated uses and realworld use cases are undesirable, and especially difficult to control for or study in apps that face the general public.

Decline of professional skills

The utilisation of AI-assisted smartphone apps and web services designed for healthcare providers with the aim of supporting clinical decision-making processes may result in a gradual decline in professional skill levels due to an increased reliance on algorithmic predictions. The propensity of humans to over-rely on a suggestion from an automated system, commonly referred to as automation bias,²⁴ poses potential risks for patients when clinicians rely heavily on AI systems to augment their clinical decisions. Previous research has demonstrated that deliberately miscalibrated algorithms have the potential to reduce the accuracy of clinicians during clinical decision-making.²⁵ As healthcare providers increasingly integrate AI-assisted apps into their practice, it is crucial to foster a culture of critical thinking, where clinicians use AI outputs as a tool for support rather than a substitute for their professional judgement. This includes continuously evaluating and monitoring the performance of AI systems, ensuring that they are used ethically and responsibly, and being mindful of the potential risks of automation bias.

Non-medical commercial influence

Consumers should remain vigilant about potential nonmedical influence from skincare corporations, as they may provide recommendations for their products through smartphone applications. A number of smartphone apps using AI are used for the analysis of skin features to provide product recommendations. As an example: apps may provide a 'skin age', 'acne score' and show 'hydrated and dehydrated zones of the face' based on visual image data, such as selfies, uploaded by users. Based on these features, apps may recommend sponsored products.^{26–29} There is also the risk that some apps may conceal their affiliation with certain brands, favour products that bring them more profit or give users unwarranted concerns based on an AI rating in order to sell products.

Data security

Dermatology related diagnostic smartphone apps and webbased services process highly sensitive patient data, creating potential privacy and security risks for users. The General Data Protection Regulation (GDPR) sets clear principles for the processing of personal data including all identifiable patient data and applies to all data controllers (including app developers). These principles include lawfulness, fairness, transparency, accuracy, integrity and confidentiality in the handling of personal data.³⁰ Developers are expected to respect these principles and to obtain informed consent from users for the processing of personal data. It is also advisable for them to conduct data protection impact assessments (DPIAs) to identify and mitigate potential risks to users. Privacy risks and security vulnerabilities may expose consumers to unnecessary harms. User data may be susceptible to data breaches due to improper handling, which can be mitigated by following the best practices suggested by recent studies. Examples of security recommendations include using Advanced Encryption Standard (AES) for data encryption, limit data retention as much as possible, and implementing strong authentication methods like two-factor validation and biometric authentication.³¹ Given the potential value of personal health data for companies, patient data could be used for company goals (e.g. improving future algorithms or be monetized [selling patient data to other companies]) without users being explicitly aware. It is important for all consumers to read the application terms of use clearly as data ownership and future use may raise ethical concerns even while complying with GDPR.

Direct and indirect costs

There are concerns about the actual direct and indirect costs to users of dermatology-related smartphone apps, which are sometimes not communicated to users. There can be different pricing models of apps such as one-time purchases, subscription-based payments or in-app purchases.¹ Some apps can be downloaded for free, but require payment for further use, deceiving potential users about the costs associated with their use. Moreover, some apps may collect and monetize user data without explicit consent or adequate security measures. These costs may affect user affordability, privacy and trust in using smartphone apps for dermatologyrelated purposes. Additionally, there may be associated costs linked to the outcomes of app-based diagnoses, such as the need for referral to a physical consultation with a dermatologist, which may entail additional expenses.

Regulatory approval

Although European dermatologists are accustomed to medication being reviewed by the European Medicines Association (EMA), diagnostic apps generally fall outside of the scope of EMA review.³² Instead, these apps need to obtain a CE (Conformité Européenne) marking from a notified body. Although the recently implemented Medical Device Regulation (MDR) has improved oversight of CE-marked diagnostic smartphone apps by at least classifying them as type IIa devices, there is still a significant risk of inappropriate apps being released for the European market. Concerns have been raised about apps that only need to meet the accuracy standard on retrospective or tailored prospective datasets set by the app developer.¹⁷ This could result in apps with insufficient accuracy and inadequate assessment of benefits and risks being used by the general population. The EADV AI Task Force considers it essential that prospective evaluation is performed in an intended use setting, for Class IIa devices. Additionally, a clear standard for the expected sensitivity

468308.30, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/jdv.19521 by University Of Siena Sist Bibliot Di Ateneo, Wiley Online Library on [25/10/2023]. See the Terms and Conditions (https://onlinelibrary.wiley.com/terms-and-conditions) on Wiley Online Library for rules of use; OA articles are governed by the applicable Creative Commons License

and specificity for different end user types (e.g. consumers, healthcare providers) has not been established. These issues pose threats to patients' health outcomes, doctors' decisionmaking, public trust in medical technology and the patientburden in public healthcare systems.

Besides concerns regarding the certification of diagnostic dermatology apps, many apps currently available for download in the iOS and Google Play Store do not even have CE-certification, meaning that unregulated apps are currently used by the general population.⁵ To the best of our knowledge, no diagnostic apps have been banned from the European market due to insufficient or lacking certification. Therefore, there appears to be a need for adequate enforcement of regulatory standards in Europe among dermatologyrelated apps supporting the diagnostic process. In contrast to Europe, the United States Food and Drug Administration (US FDA) has a stricter assessment process to evaluate mobile apps by taking a wider perspective of harm where 'functionality could pose a risk to a patient's safety if the mobile app were to not function as intended'.³³ No skin cancer risk stratification smartphone app intended for use by patients and consumers has received FDA approval to date due to this rigorous assessment, but many apps are available on the US app store (Android and Apple iOS) despite the early promise that the Federal Trade Commission³⁴ might increase enforcement. The European regulatory framework may benefit from the US perspective and by incorporating an expert panel of dermatologists with other stakeholders in the discussion of standards of quality and CE-marking procedure of AI-based diagnostic (risk-scoring) smartphone apps. To ensure safe and effective use of new technology, it is crucial to evaluate the benefits and risks of implementation across various clinical and non-clinical use cases and for different end-users.

Furthermore, the lack of explainability of AI algorithms makes it difficult for regulators to evaluate the trustworthiness and safety of AI algorithms. It is challenging to determine whether a model has learned meaningful features and patterns or merely memorized noise in the data. Without a clear understanding of how an algorithm reaches its conclusions, it is hard to design appropriate regularisation techniques that effectively balance generalisation and overfitting while preserving the model's predictive accuracy.

Multidisciplinary implementation

The Task Force considers that AI algorithms, with appropriate education on correct usage for end-users, integrated into smartphone apps and web-based services have the potential to serve as reliable screening or supporting tools in specific situations in the near future. For example, they may be useful for screening and monitoring of suspicious skin lesions. These apps may provide increased access to dermatological care, particularly in rural areas with a limited number of dermatologists, and may also help to improve early detection of skin cancer and other skin conditions. Patients may further benefit from this technology by receiving advice regarding skin conditions from home without having to physically visit a dermatologist. However, to achieve these benefits, it is important that the apps are designed with the views, needs and capabilities of their potential users in mind. This includes an accessible, intuitive and easy-to-use design.³⁵ It is also crucial to incorporate the views of other relevant stakeholders in the design and implementation process. The implementation of diagnostic smartphone apps could disrupt existing patient journeys, depending on how and where they are positioned. For instance, the implementation of a skin cancer diagnostic app by a health insurer can disrupt the way patients visit their GP or dermatologist, for example, it may become very difficult for non-specialized GPs to dismiss a patient with an obviously benign skin lesion when a highsensitivity low-specificity diagnostic algorithm has raised a skin cancer concern. Therefore, a multidisciplinary perspective is necessary for successful implementation, which could involve primary care providers, clinicians, patient associations, app developers, regulators and health insurers.

RECOMMENDATIONS

The main recommendations, and corresponding subrecommendations, of the EADV AI Task Force regarding

 TABLE 1
 Main recommendations, and corresponding subrecommendations, of the EADV AI Task Force regarding AI-assisted smartphone apps and web-based services for skin disease.

Main recommendations

 To ensure user trust, app developers should prioritize transparency in data quality, accuracy, intended use, privacy and costs.

Subrecommendations

- 1.1 To avoid underrepresentation of certain skin tones in training data, image training data should include relevant images and patient-level contextual information from the target population.
- 1.2 To ensure consistent accuracy for all skin tones and devices (both hardware and software), diagnostic accuracy should be verified in the relevant target population.
- 1.3. Developers must clearly state to users the extent of validation that has been carried out, including information regarding the target population, accuracy outcomes (such as sensitivity and specificity), impact on patient or consumer decision-making and evaluated impact on overall health outcomes. If any populations or devices have not undergone rigorous assessment, this fact must be disclosed to users in an explicit manner.
- 1.4 To enhance accountability and traceability, it is recommended that developers implement mechanisms enabling users to report errors or discrepancies and establish a clear and accessible appeals process.
- 1.5 Privacy risks should be minimized by implementing 'privacy by design' principles.
- 1.6 To avoid unexpected costs, potential users should be informed of any costs related to app use prior to downloading.
- To respect user privacy, users should explicitly consent if their data is being monetized for commercial purposes.
- 1.8 To ensure effectiveness, post-clearance studies should be included as mandatory components of future implementation strategies to provide insight into the population-wide impact of diagnostic smartphone apps and web-based services.
- 1.9 App developers should include an appeal mechanism to address incorrect outcomes and provide users with a means to challenge and rectify such situations.
- 1.10 Human preferences should be incorporated during the development of algorithms to improve diagnostic decision support.

- Apps and web-based services should ensure a uniform user experience for diverse groups of patients
- 2.1 Apps should perform at comparable accuracy across diverse groups of patients and devices in which they may be expected to be used.
- 2.2 The design and functionality of dermatology apps should be accessible to diverse user groups.
- 2.3 The exclusion of subpopulations based on skin tone, age, technological illiteracy and disabilities must be avoided.
- 2.4 Multidisciplinary implementation should be pursued to foster collaboration and innovation among different stakeholders involved in AI smartphone apps in dermatology.

- European authorities should adopt a rigorous and consistent regulatory framework for dermatology apps to ensure their safety and accuracy for users.
- 3.1 An expert panel of dermatologists should ideally be considered part of the evaluation process to ensure a comprehensive risk– benefit evaluation of the approval of novel smartphone apps.
- 3.2 Explainability of AI algorithms should be prioritized, and a panel of dermatological experts should verify the underlying principles of the algorithms.
- 3.3 Active surveillance of uncertified or improperly certified apps in popular app stores should be conducted and these apps should be banned to protect users.
- 3.4 App stores (e.g. Apple App Store, Google Play Store) should only allow access to AIapps that have been correctly CE-marked.

AI-assisted smartphone apps and web-based services for skin disease are outlined in Table 1.

OUTLOOK AND FUTURE PERSPECTIVES

As we enter an era of rapid advancements in AI and digital health, dermatology-related diagnostic smartphone apps have the potential to revolutionize patient journeys. However, it is crucial to approach this technology with a positive yet realistic outlook that highlights both the opportunities and challenges that lie ahead. Currently, there is a strong need for high-quality evidence to assess the efficacy, safety and risk-benefit of diagnostic smartphone apps for skin disease.

While the primary use of these apps may lie outside the dermatologist's office, their potential to impact patient care is significant. Dermatologists play a pivotal role in assessing and improving app implementations, ensuring that patients receive accurate, reliable and useful advice for skin conditions. By staying well-informed about the available software, dermatologists can effectively advise patients on the appropriate use of these apps, ultimately benefiting patient outcomes and fostering a sense of empowerment in self-care. Moreover, fostering a positive and collaborative relationship between app developers and dermatologists is crucial for the successful implementation of these apps, which is actively endorsed by the EADV AI Task Force. By providing constructive feedback and guidance, dermatologists can help developers refine their products, ensuring that they meet the needs of end-users and align with clinical practice. This collaborative approach will promote innovation, user adoption and facilitate the integration of AI-powered apps and web-based services into dermatology and the healthcare system as a whole.

The reliability and accessibility of dermatology apps are expected to be enhanced through advancements in AI algorithms and the adoption of more user-centred design principles. By focusing on the needs of diverse patient populations and ensuring a consistent user experience across different devices, these apps will be better equipped to address disparities in access to dermatological care. In the future, these apps may even serve as reliable screening and triage tools for patients and improve early detection of skin cancer and other skin conditions, further underscoring the importance of continuous improvement and innovation in this space. However, to ensure the safe and effective use of AI in these use cases, proper education on its correct usage is essential, especially for lay users. One way to achieve this goal is through AI-assisted education programs that improve end-users' ability to detect suspicious skin lesions. The EADV AI Task Force aims to support these efforts by developing and promoting best practices for AI-enabled dermatology tools, including AI-assisted education. Additionally, it is essential for researchers to address challenges related to the reliability, robustness, explainability and causality of AI algorithms

to ensure the safety and effectiveness of diagnosing skin conditions.

Regulatory bodies are advised to consider adopting a stringent and consistent regulatory framework for dermatology smartphone applications with the aim of protecting the interests of patients and healthcare providers. The inclusion of an expert panel of dermatologists in the evaluation process, as is the case in the United States, could facilitate a comprehensive benefit-risk assessment during the app's approval phase. In addition, established guidelines like the Checklist for Evaluation of Image-based AI Reports in Dermatology (CLEAR-Derm) can aid in the comprehensive assessment of AI algorithms that form the foundation of AI-assisted apps and web-based services.³⁶ With the introduction of new technologies, traditional frameworks need to be adapted, taking into account different clinical scenarios in which an app or web-based platform may be used. While appropriate standards and thresholds that should be achieved remain unclear, the overall risks and benefits of implementing the app should be balanced for different use case scenarios with different end users. Moreover, active monitoring of uncertified applications within prevalent app stores, and the subsequent removal of those failing to meet regulatory standards, may enhance user safety and sustain public confidence in medical technology. Monitoring should be prioritized according to adoption (number of downloads), ensuring that apps that may cause the most harm are evaluated first.

In conclusion, the utilisation of AI-assisted smartphone apps and web-based services in diagnosing and treating skin diseases has the potential to greatly benefit patients in their dermatology journeys. By prioritising innovation, fostering collaboration and implementing effective regulations, we can ensure the successful integration of these apps into clinical practice.

ACKNOWLEDGEMENTS

We acknowledge the remaining members of the EADV AI Task Force Veronique Bataille, Brigid Betz-Stablein, Titus Brinker, Konstantinos Liopyris, Caterina Longo, Giovanni Pellacani, Lidia Rudnicka, Marta Sar-Pomian, Wilhelm Stolz and Alexander Zink for their support and endorsement of this scientific manuscript.

FUNDING INFORMATION

None.

CONFLICT OF INTEREST STATEMENT

TS reports receiving speaker fees from Janssen-Cilag, UCB, Pfizer, AbbVie, consulting fees from Mylan by, and works on research projects which were funded by an unrestricted research grant from SkinVision by. H.K. reports speaker fees from Fotofinder, non-financial support from Heine, Fotofinder and Derma Medical, licence fees from Heine, Casio, MetaOptima and Barco. MC reports consulting fees from Global Dermatology and Surgivance (all outside of this work). PG reports receiving some honoraria from Metaoptima, PTY and travel stipend from La Roche Posay. HAH declares being a consultant and advisor and/or receiving speaking fees and/or grants and/or served as an investigator in clinical trials for Almirall, Beiersdorf AG, Eli Lilly, FotoFinder Systems, Galderma, Heine Optotechnik GmbH, Magnosco GmbH, Pierre Fabre Pharma Scibase AB. NK is CEO and co-founder of MelaTech ApS. AAN declares being a consultant and advisor and/or receiving speaking fees and/ or grants and/or served as an investigator in clinical trials for AbbVie, Almirall, Amgen, Biomed, Bristol Myers Squibb, Boehringer Ingelheim, Celgene, Eli Lilly, Galderma, GlaxoSmithKline, LEO Pharma, Louis-Widmer AG, Janssen-Cilag, MSD, Novartis, Pfizer, Pierre Fabre Pharma, Regeneron, Sandoz, Sanofi, UCB. He is minority shareholder of Derma2Go AG. VR received a KL2 award from NIH NCATS. HPS is a shareholder of MoleMap NZ Limited and e-derm consult GmbH and undertakes regular teledermatological reporting for both companies. HPS is a Medical Consultant for Canfield Scientific Inc, MoleMap Australia Pty Ltd, Blaze Bioscience Inc, and a Medical Advisor for First Derm. PT reports grants from Lilly, consulting fees from Silverchair, and speaker honoraria from Lilly, FotoFinder and Novartis, all outside the submitted work. JM declares being co-founder of Athena Tech and consultant and medical advisor of Dermavision Solutions. He had grants from Leo Pharma, Almirall. Personal fees from SunPharma, AMGEN, Almirall, Leo Pharma, Isdin, La Roche Posay, Roche, Pierre Fabre, BMS, ISDIN, outside the submitted work. All other co-authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analysed.

ETHICS STATEMENT

Ethics approval was not required for this publication as it involves the interpretation of publicly available data and does not involve any direct human or animal subjects.

ORCID

Tobias E. Sangers https://orcid.org/0000-0003-0948-5801 Harald Kittler D https://orcid.org/0000-0002-0051-8016 Ralph P. Braun () https://orcid.org/0000-0003-1253-8206 Alessandra Cartocci 🕩 https://orcid. org/0000-0002-1818-6275 Marc Combalia 🗅 https://orcid.org/0000-0001-5237-4256 Pascale Guitera 🗅 https://orcid.org/0000-0001-9519-110X Holger A. Haenssle D https://orcid. org/0000-0001-7255-3104 Niels Kvorning b https://orcid.org/0000-0002-8034-6727 Aimilios Lallas 🕩 https://orcid.org/0000-0002-7193-0964 *Cristian Navarrete-Dechent* bhttps://orcid. org/0000-0003-4040-3640 Alexander A. Navarini 🕩 https://orcid. org/0000-0001-7059-632X Sebastian Podlipnik 🗅 https://orcid. org/0000-0003-4150-0522

H. Peter Soyer b https://orcid.org/0000-0002-4770-561X Linda Tognetti b https://orcid.org/0000-0002-6691-4310 Philipp Tschandl b https://orcid.org/0000-0003-0391-7810 Josep Malvehy b https://orcid.org/0000-0002-6998-914X

REFERENCES

- Kong FW, Horsham C, Ngoo A, Soyer HP, Janda M. Review of smartphone mobile applications for skin cancer detection: what are the changes in availability, functionality, and costs to users over time? Int J Dermatol. 2021;60:289–308. https://doi.org/10.1111/ijd.15132
- de Carvalho TM, Noels E, Wakkee M, Udrea A, Nijsten T. Development of smartphone apps for skin cancer risk assessment: Progress and promise. JMIR Dermatol. 2019;2(1):e13376.
- Esteva A, Kuprel B, Novoa RA, Ko J, Swetter SM, Blau HM, et al. Dermatologist-level classification of skin cancer with deep neural networks. Nature. 2017;542(7639):115–8.
- Freeman K, Dinnes J, Chuchu N, Takwoingi Y, Bayliss SE, Matin RN, et al. Algorithm based smartphone apps to assess risk of skin cancer in adults: systematic review of diagnostic accuracy studies. BMJ. 2020;368:m127.
- Sun MD, Kentley J, Mehta P, Dusza S, Halpern AC, Rotemberg V. Accuracy of commercially available smartphone applications for the detection of melanoma. Br J Dermatol. 2022;186(4):744–6.
- 6. Jahn AS, Navarini AA, Cerminara SE, Kostner L, Huber SM, Kunz M, et al. Over-detection of melanoma-suspect lesions by a CE-certified smartphone app: performance in comparison to dermatologists, 2D and 3D convolutional neural networks in a prospective data set of 1204 pigmented skin lesions involving patients' perception. Cancers. 2022;14(15):3829.
- Ternov NK, Christensen AN, Kampen PJT, Als G, Vestergaard T, Konge L, et al. Generalizability and usefulness of artificial intelligence for skin cancer diagnostics: an algorithm validation study. JEADV Clin Pract. 2022;1(4):344–54.
- Rotemberg V, Kurtansky N, Betz-Stablein B, Caffery L, Chousakos E, Codella N, et al. A patient-centric dataset of images and metadata for identifying melanomas using clinical context. Sci Data. 2021;8(1):34.
- 9. Combalia M, Codella N, Rotemberg V, Carrera C, Dusza S, Gutman D, et al. Validation of artificial intelligence prediction models for skin cancer diagnosis using dermoscopy images: the 2019 international skin imaging collaboration grand challenge. Lancet Digit Health. 2022;4(5):e330–9.
- Gessert N, Nielsen M, Shaikh M, Werner R, Schlaefer A. Skin lesion classification using ensembles of multi-resolution EfficientNets with meta data. Methods X. 2020;7:100864.
- 11. Winkler JK, Sies K, Fink C, Toberer F, Enk A, Deinlein T, et al. Melanoma recognition by a deep learning convolutional neural network-performance in different melanoma subtypes and localisations. Eur J Cancer. 2020;127:21–9.
- 12. Phillips M, Marsden H, Jaffe W, Matin RN, Wali GN, Greenhalgh J, et al. Assessment of accuracy of an artificial intelligence algorithm to detect melanoma in images of skin lesions. JAMA Netw Open. 2019;2(10):e1913436-e.
- Sangers T, Reeder S, van der Vet S, Jhingoer S, Mooyaart A, Siegel DM, et al. Validation of a market-approved artificial intelligence Mobile health app for skin cancer screening: a prospective multicenter diagnostic accuracy study. Dermatology. 2022;238(4):649–56.
- Navarrete-Dechent C, Dusza SW, Liopyris K, Marghoob AA, Halpern AC, Marchetti MA. Automated dermatological diagnosis: hype or reality? J Invest Dermatol. 2018;138(10):2277–9.
- Daneshjou R, Vodrahalli K, Novoa RA, Jenkins M, Liang W, Rotemberg V, et al. Disparities in dermatology AI performance on a diverse, curated clinical image set. Sci Adv. 2022;8(32):eabq6147.
- Wen D, Khan SM, Ji XA, Ibrahim H, Smith L, Caballero J, et al. Characteristics of publicly available skin cancer image datasets: a systematic review. Lancet Digit Health. 2022;4(1):e64–74.
- Matin RN, Dinnes J. AI-based smartphone apps for risk assessment of skin cancer need more evaluation and better regulation. Br J Cancer. 2021;124(11):1749–50.

4683083, 0, Downloaded from https://onlinelibrary.wiley.com/doi/10.1111/jdv.19521 by University Of Siena Sist Bibliot Di Ateneo, Wiley Online Library on [25/10/2023]. See the Terms and Conditions

(https

library.wiley.com

and

) on Wiley Online Library for rules

of use; OA articles

are governed by the applicable Creative Commons

- Sangers TE, Nijsten T, Wakkee M. Mobile health skin cancer risk assessment campaign using artificial intelligence on a population-wide scale: a retrospective cohort analysis. J Eur Acad Dermatol Venereol. 2021;35(11):e772-4.
- Smak Gregoor AM, Sangers TE, Bakker LJ, Hollestein L, Uyl de Groot CA, Nijsten T, et al. An artificial intelligence based app for skin cancer detection evaluated in a population based setting. NPJ Digit Med. 2023;6(1):90.
- 20. European Commision. Ethics guidelines for trustworthy AI. https:// digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trust worthy-ai [Last accessed 17-05-2023].
- Sangers TE, Wakkee M, Moolenburgh FJ, Nijsten T, Lugtenberg M. Towards successful implementation of artificial intelligence in skin cancer care: a qualitative study exploring the views of dermatologists and general practitioners. Arch Dermatol Res. 2023;315(5):1187–95.
- 22. Hauser K, Kurz A, Haggenmüller S, Maron RC, von Kalle C, Utikal JS, et al. Explainable artificial intelligence in skin cancer recognition: a systematic review. Eur J Cancer. 2022;167:54–69.
- Barata C, Rotemberg V, Codella NCF, Tschandl P, Rinner C, Akay BN, et al. A reinforcement learning model for AI-based decision support in skin cancer. Nat Med. 2023;29(8):1941–6.
- 24. United States Food and Drug Administration. Clinical Decision Support Software: Guidance for Industry and Food and Drug Administration Staff. https://www.fda.gov/regulatory-information/ search-fda-guidance-documents/clinical-decision-support-software [Last accessed 17-05-2023].
- Tschandl P, Rinner C, Apalla Z, Argenziano G, Codella N, Halpern A, et al. Human-computer collaboration for skin cancer recognition. Nat Med. 2020;26:1229–34.
- Vichy. Skin ConsultAI. https://www.vichyusa.com/skin-care-analy sis-ai.html [Last accessed 17-05-2023].
- Olay. Skin Advisor. https://www.olay.com/skin-advisor [Last accessed 17-05-2023].
- La Roche Posay Spotscan. https://www.laroche-posay.co.uk/default/ spotscan.html.[Last accessed 17-05-2023].
- 29. Ouellette S, Rao BK. Usefulness of smartphones in dermatology: a US-based review. Int J Environ Res Public Health. 2022;19(6):3553. https://doi.org/10.3390/ijerph19063553
- 30. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with

regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). https://eur-lex.europa.eu/legal-content/EN/ TXT/PDF/?uri=CELEX:32016R0679 [Last accessed 17-05-2023].

- Martínez-Pérez B, de la Torre-Díez I, López-Coronado M. Privacy and security in mobile health apps: a review and recommendations. J Med Syst. 2015;39(1):181.
- European Medicines Agency. Medical devices. https://www.ema.europa.eu/en/human-regulatory/overview/medical-devices. [Last accessed 17-05-2023].
- 33. United States Food and Drug Administration. Policy for Device Software Functions and Mobile Medical Applications. https://www. fda.gov/regulatory-information/search-fda-guidance-documents/ policy-device-software-functions-and-mobile-medical-applications. [Last accessed 17-05-2023].
- Federal Trade Commission. https://www.ftc.gov/news-events/news/ press-releases/2015/02/ftc-cracks-down-marketers-melanoma-detec tion-apps [Last accessed 17-05-2023].
- 35. Sangers TE, Wakkee M, Kramer-Noels EC, Nijsten T, Lugtenberg M. Views on mobile health apps for skin cancer screening in the general population: an in-depth qualitative exploration of perceived barriers and facilitators*. Br J Dermatol. 2021;185(5):961–9.
- 36. Daneshjou R, Barata C, Betz-Stablein B, Celebi ME, Codella N, Combalia M, et al. Checklist for evaluation of image-based artificial intelligence reports in dermatology: CLEAR Derm consensus guidelines from the international skin imaging collaboration artificial intelligence working group. JAMA Dermatol. 2022;158(1):90–6.

How to cite this article: Sangers TE, Kittler H, Blum A, Braun RP, Barata C, Cartocci A, et al. Position statement of the EADV Artificial Intelligence (AI) Task Force on AI-assisted smartphone apps and web-based services for skin disease. J Eur Acad Dermatol Venereol. 2023;00:1–9. <u>https://doi.org/10.1111/jdv.19521</u>